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(54) Title: PROSTHETIC AORTIC HEART VALVES

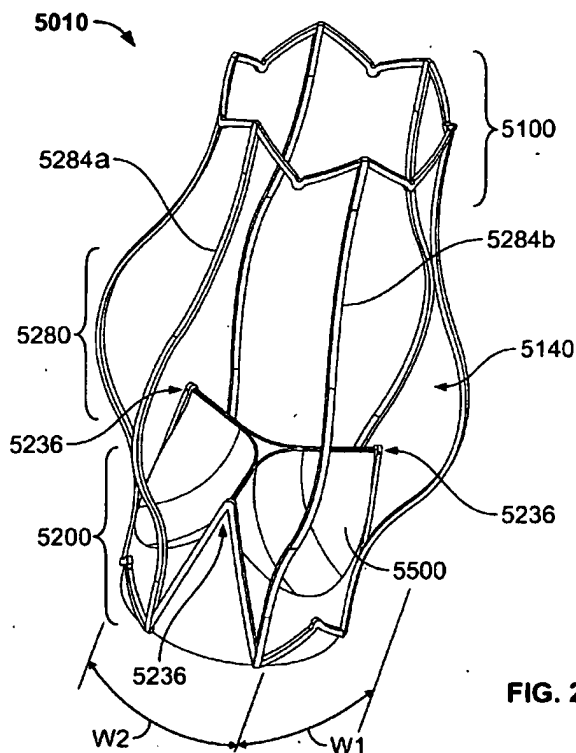


FIG. 2

(57) Abstract: A prosthetic aortic valve includes an annular, annulus inflow portion that is designed to reside in or near the patient's native aortic valve annulus, and an annular, aortic outflow portion that is designed to reside in the patient's aorta downstream from at least a portion of the aortic sinus. The annulus inflow portion and the aortic outflow portion are connected to one another by a plurality of connecting struts that are confined to regions near the commissures of the patient's native aortic valve. The connecting struts are designed to bulge out into the aortic sinus to help anchor the prosthetic valve in place. The valve is circumferentially collapsible to a relatively small diameter for less-invasive delivery into the patient. The valve circumferentially expands to a larger operational diameter when deployed at the implant site.



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PROSTHETIC AORTIC HEART VALVES

[0001] This application claims the benefit of U.S. provisional patent application No. 60/966,113, filed August 24, 2007, which is hereby incorporated by  
5 reference herein in its entirety.

Background of the Invention

[0002] PCT patent application No. PCT/US08/07015, filed June 4, 2008, shows prosthetic heart valves that are annularly collapsible for delivery into a patient,  
10 and then re-expandable at the implant site in the patient. (The above document will be referred to hereinafter as the above-mentioned reference, and it is hereby incorporated by reference herein in its entirety.) The prosthetic heart valves shown and  
15 described in the above-mentioned reference typically include an annular supporting structure or stent frame (e.g., of a highly elastic metal such as nitinol). This stent frame or stent typically includes an annulus inflow portion and an aortic outflow portion that is  
20 generally coaxial with the annulus inflow portion and spaced downstream (in terms of blood flow through the implanted valve) from the annulus inflow portion. The

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annulus inflow and aortic outflow portions are preferably connected to one another substantially solely by connecting struts that extend between the annulus inflow and aortic outflow portions adjacent to the commissure regions (also known as commissure posts having commissure tips) of the valve. By confining these connecting struts between the annulus inflow and aortic outflow portions to close proximity to the commissure tip regions, the circumferential space between annularly adjacent commissure tips is left relatively open, which (in the case of aortic valve use) helps the prosthesis avoid occluding the ostia of the coronary arteries.

[0003] Valves of this general type are intended for delivery into a patient at an implant site to which the surgeon may not have direct open access, e.g., for suturing the implanted valve in place. Good self-anchoring of the valve at the implant site is therefore important, and there may be self-anchoring improvements that can be made relative to embodiments that are shown in the above-mentioned reference.

#### Summary of the Invention

[0004] A prosthetic aortic valve in accordance with the invention typically includes an annular stent frame and a plurality of valve leaflets supported by a portion of the stent. The stent typically includes an annulus inflow portion configured for disposition adjacent a patient's native aortic valve annulus. The leaflets are typically supported by the annulus inflow portion. The stent typically further includes an aortic outflow portion configured for disposition in the patient's native aorta downstream from at least a

portion of the patient's native valsalva sinus (also sometimes called the sinus of valsalva). The stent typically still further includes a plurality of connecting struts that constitute substantially the sole connection between the annulus inflow portion and the aortic outflow portion. The annulus inflow portion typically defines a plurality of commissure tips that are spaced from one another in the annular direction around the annulus inflow portion. The commissure tips are the features of the annulus inflow portion that are closest to the aortic outflow portion. Each of the above-mentioned connecting struts is connected to the annulus inflow portion only at points that are farther from the aortic outflow portion than the commissure tips. In addition, each of the connecting struts is adjacent to an associated one of the commissure tips, and at least one of the struts is positioned for disposition adjacent each side of each of the patient's native aortic valve commissure tips. Each of the connecting struts is constructed to bulge radially outwardly like (and into) the valsalva sinus when the valve is in use in a patient.

[0005] Further features of the invention, its nature and various advantages, will be more apparent from the accompanying drawings and the following detailed description.

#### Brief Description of the Drawings

[0006] FIG. 1 is a simplified perspective or isometric view of an illustrative embodiment of some components of a prosthetic heart valve in accordance with the invention, in a first possible operating condition of those components.

[0007] FIG. 2 is a simplified perspective or isometric view of a structure like that shown in FIG. 1, in another possible operating condition of that structure.

5 [0008] FIG. 3 is a simplified cross-sectional view of a patient's native tissue, with some components of an implanted valve of this invention visible in that native tissue structure.

[0009] FIG 4 is a view similar to FIG. 2 for another  
10 illustrative embodiment in accordance with the invention.

[0010] FIG. 5 is a view similar to FIG. 2 for yet another illustrative embodiment in accordance with the invention.

15 [0011] FIG. 6 is a view similar to FIG. 2 for still another illustrative embodiment in accordance with the invention.

[0012] FIG. 7a is a view similar to part of FIG. 2 for yet another illustrative embodiment in accordance  
20 with the invention. FIG. 7a shows the leaflets of the valve open but greatly simplified. FIG. 7a also shows other possible components added.

[0013] FIG. 7b is a view similar to FIG. 7a for another illustrative embodiment in accordance with the  
25 invention.

[0014] FIG. 8 is a view similar to FIG. 2 for still another illustrative embodiment in accordance with the invention.

[0015] FIG. 9 shows a portion of the FIG. 8  
30 embodiment in another operating condition of the apparatus.

[0016] FIG. 10 is a simplified elevational view of a portion of yet another illustrative embodiment in

accordance with the invention. FIG. 10 shows the depicted component after it has been cut along an axis that is vertical in FIG. 10 and then laid out flat in the plane in which FIG. 10 is drawn.

5 [0017] FIG. 11 is an enlargement of a representative portion of what is shown in FIG. 10.

[0018] FIG. 12 shows the FIG. 11 structure in another operating condition.

10 [0019] FIG. 13 is a view similar to FIG. 10 for another illustrative embodiment in accordance with the invention.

[0020] FIG. 14 is a simplified view looking down on the inflow portion of an illustrative embodiment of a prosthetic heart valve in accordance with the  
15 invention.

[0021] FIG. 15 is a simplified view looking down on the inflow portion of another illustrative embodiment of a prosthetic heart valve in accordance with the invention.

20 [0022] FIG. 16 is a view similar to FIG. 13 for another illustrative embodiment in accordance with the invention.

#### Detailed Description

[0023] Many of the principles employed in the  
25 prosthetic valves that are shown and described in the above-mentioned reference can be employed in valves in accordance with this invention. Accordingly, the descriptions of some features herein can be somewhat abbreviated because more complete information is  
30 already available from the above-mentioned reference. To facilitate comparison, the reference numbers that are used herein for components that are at least

generally similar to components in the above-mentioned reference are often (although perhaps not always) related by integer multiples of 1000 to the reference numbers used for those generally similar components in the above-mentioned reference. Thus, for example, component 5010 herein is generally similar to any of components 10, 1010, 2010, 3010, 4010, 5010, etc., in the above-mentioned reference.

[0024] FIG. 1 shows some components of an illustrative prosthetic heart valve in accordance with the invention in an annularly or circumferentially collapsed condition for delivery into a patient via relatively small-diameter delivery apparatus. (FIG. 1 has been simplified as explained in more detail in the next paragraph.) Such small-diameter delivery can be used to avoid full open-chest/open-heart surgery. FIG. 2 shows a valve generally like the valve shown in FIG. 1 (although with some differences from what is shown in FIG. 1) after annular or circumferential re-expansion (e.g., via the use of highly-elastic, self-expansion). FIG. 2 thus shows a valve in its deployed condition (i.e., the condition it has when implanted in a patient).

[0025] All of the many embodiments shown and described in this specification are annularly or circumferentially collapsible to a delivery condition like that generally illustrated by FIG. 1, and then annularly or circumferentially re-expandable to an implanted or deployed condition like that generally illustrated by FIG. 2.

[0026] The valves shown in FIGS. 1 and 2 are intended for implanting within a patient's native aortic valve to mitigate impaired functioning of the



native valve. FIGS. 1 and 2 do not necessarily show all features or components of complete valves. For example, some layers of material (e.g., fabric and/or tissue) that may be used around the outside of certain portions of these valves are not shown in FIGS. 1 and 2 to better reveal possible constructional features of other components of the valves. In particular, FIGS. 1 and 2 primarily show the collapsible/expandable, metal, stent frame 5010 of the depicted valves, and the flexible leaflets 5500 of these valves. (Again, fabric material (not shown) can be used outside or inside stent frame 5010 at the inflow section of the stent.) Examples of suitable materials for leaflets 5500 include biological tissue, polymer, thin metal, reinforced polymer, etc. As used herein, the term "biological tissue" includes such things as actual harvested porcine valves, bovine pericardium, and the like.

[0027] As in the above-mentioned reference, stent 5010 includes an aortic outflow portion 5100 and an annulus inflow portion 5200. Portions 5100 and 5200 are connected to one another substantially solely by at least one connecting strut 5284. All of these structures (5100, 5200, and 5284) are annularly or circumferentially collapsible (FIG. 1) and re-expandable (FIG. 2). This includes leaflets 5500. When the valve is in place in a patient's native aortic valve, the prosthetic valve is re-expanded as shown in FIG. 2. When the valve is thus re-expanded at the implant site in the patient, annulus inflow portion 5200 is typically adjacent the patient's native aortic valve annulus, aortic outflow portion 5100 is in the aorta downstream from the valsalva sinus (or downstream

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from at least part of the valsalva sinus), and connecting struts 5284 pass through the valsalva sinus (or through at least part of the valsalva sinus). In addition, respective connecting struts 5284 preferably  
5 pass near and on each side of each of the patient's native valve commissures. This last point will be described in greater detail later in this specification. Because portion 5100 thus resides in the patient's aorta when the valve is implanted,  
10 portion 5100 is generally referred to herein as the aortic outflow portion.

[0028] Annulus inflow portion 5200 includes three commissure posts or tip regions 5236 that are equally spaced from one another around the valve. In the  
15 FIG. 2 embodiment, for example, each of the commissure tips 5236 is at the free apex of a V-shaped commissure post structure that extends down from the tip as viewed in FIG. 2. Each of these V-shaped commissure post structures is cantilevered from at least an associated  
20 pair of annularly spaced points on remaining structure of annulus inflow portion 5200. Cantilevering the commissure posts in this way facilitates giving the commissure posts desirable flexibility, which includes flexibility in a direction that is radial of the valve  
25 at the location of the tip or free end of each commissure post.

[0029] Adjacent each of commissure tips 5236, there is an associated pair of connecting struts 5284a and 5284b. One of these struts 5284a is on one side of the  
30 associated commissure tip 5236 in a circumferential direction around the valve, and the other strut 5284b is on the other side of the associated commissure tip in a circumferential direction around the valve. Each

of these struts 5284 connects to the annulus inflow portion 5200 at a point that is well below the associated commissure tip 5236. As in the above-mentioned reference, this makes it possible for the commissure post structure below each tip 5236 to be desirably flexible relatively independently of struts 5284. It also facilitates giving commissure post structures 5236 and struts 5284 shapes in the radial direction (i.e., inwardly and outwardly of the valve as a whole) that can be relatively independent of one another. For example, commissure post structures 5236 can go relatively straight up from the base of annulus inflow portion 5200, while struts 5284 can bulge radially out from the geometric cylindrical surface in which the commissure post structures lie. (The entire population of connecting struts 5284 in a valve may sometimes be referred to collectively by reference number 5280.)

[0030] The connecting struts 5284a and 5284b that are adjacent to each commissure tip 5236 can remain relatively close to one another and to that commissure tip as they extend to aortic outflow portion 5100. Thus, for example, in the annular (circumferential) direction around the expanded valve (e.g., as in FIG. 2), and at the level (in the axial direction along the valve) of commissure tips 5236, the struts 5284a and 5284b that are associated with each commissure tip 5236 tend to be closer to one another than they are to the circumferentially nearest strut 5284 that is associated with another commissure tip. This helps to give the valve relatively large openings 5140 between the struts 5284 that are associated with annularly adjacent ones of the commissure tips. This may be

desirable to help the valve avoid occluding the coronary ostia of the patient's coronary arteries. These ostia are located in the valsalva sinus approximately midway between axial projections of certain of the native aortic valve commissures (see FIG. 3, which is discussed in more detail later in this specification).

[0031] To quantify an aspect of what is said above, at the level of commissure tips 5236 in the circumferentially expanded valve shown in FIG. 2, the width W1 of the opening 5140 between the struts 5284 associated with two annularly (or circumferentially) adjacent commissures is preferably greater than the width W2 between the struts associated with a given commissure. More preferably W2 is less than about one-half of W1.

[0032] FIG. 3 shows the approximate cross-sectional shape of a typical native valsalva sinus 20. Axial projections of the commissures of the native aortic valve are indicated at 22. Locations of coronary artery ostia are indicated at 24. Between each annularly adjacent pair of commissure projections 22, valsalva sinus 20 has an outwardly bulging lobe. The two connecting struts 5284a and 5284b associated with each prosthetic valve commissure pass axially through the valsalva sinus on respective opposite sides of the commissure projection 22 that is associated with the prosthetic valve commissure 5236 that is aligned with that projection 22. These struts 5284a and 5284b also bulge radially out to follow the bulge of the adjacent valsalva sinus tissue (see again FIG. 2). From this it will be appreciated that the shape and locations of struts 5284a and 5284b can help to anchor the

prosthetic valve in the desired axial and angular location in the patient. The presence of a pair of struts 5284a and 5284b adjacent to each side of each commissure projection 22 can help prevent the

5 prosthetic valve from rotating in the patient about the longitudinal axis of the valve. In addition, the outward bulging of struts 5284 into the outward bulging of the valsalva sinus lobes can help prevent the prosthetic valve from moving in either direction along

10 the longitudinal axis of the valve. These anchoring aspects of connecting struts 5284 passing through valsalva sinus 20 can be in addition to other anchoring aspects that the prosthetic valve may have (e.g., as shown and described in the above-mentioned reference).

15 [0033] When deployed in a patient, all of the various prosthetic valve embodiments that are shown and described in this specification have outwardly bulging connecting struts 5284 like those shown in FIG. 2, with spacing (e.g., W1 and W2) like that shown in FIG. 2,

20 and with positioning of the struts relative to native valve commissure projections 22 like that shown in FIG. 3.

[0034] FIG. 4 shows an alternative embodiment of stent frame 5010 (now labelled 5010a in FIG. 4).

25 Although there are some differences between stent 5010a and stent 5010, the same reference numbers are generally used for generally similar parts of both embodiments (i.e., the embodiment of FIG. 4 and the earlier-described embodiment of FIGS. 1 and 2).

30 Whereas in the embodiment of FIGS. 1 and 2 both of aortic outflow portion 5100 and annulus inflow portion 5200 are annularly continuous all the way around stent 5010, in the FIG. 4 embodiment stent 5010a

is annularly continuous as a whole, but each of portions 5100 and 5200 has several interruptions in the annular (circumferential) direction. In particular, where portion 5100 extends between two annularly adjacent connecting struts 5284, portion 5200 does not extend between those two struts; and where portion 5200 extends between two annularly adjacent struts 5284, portion 5100 does not extend between those two struts. In other respects the prosthetic heart valve shown in FIG. 4 can be similar to what is shown in FIGS. 1 and 2, and it can implant in a patient similarly to what is shown in FIG. 3.

[0035] An embodiment like that shown in FIG. 4 may fit better in certain patients. For example, it may fit better in an irregular native aortic valve annulus (e.g., an annulus that is made irregular by a congenital defect or by the presence of calcified native leaflet material). A purpose for this embodiment is to provide flexibility in sizing of the distal section (e.g., aortic outflow portion 5100). The intention of the inflow side is not to conform to native geometry, but rather to remodel that geometry to allow the prosthetic valve to function optimally. The presence of hard calcification can impact the final deployed shape. This design allows some balance between remodeling and conforming.

[0036] FIG. 5 shows another alternative embodiment of stent frame 5010 (now referenced 5010b in FIG. 5). Again, the same reference numbers used earlier are used again for generally similar elements of FIG. 5. In FIG. 5 aortic outflow portion 5100 is annularly continuous (as in FIGS. 1 and 2), but annulus inflow portion 5200 is annularly interrupted in the same way

that the annulus inflow portion is interrupted in FIG. 4. In other respects the FIG. 5 embodiment may be similar to the previously described embodiments, and it can be implanted in a patient as illustrated in part in

5 FIG. 3. Like the embodiment of FIG. 4, the embodiment of FIG. 5 may fit better in certain patients, such as patients with an irregular native aortic valve annulus.

[0037] Note that in any of the embodiments shown and described herein, the stent frame can be provided with

10 eyelets, apertures, or other features that facilitate attachment of the leaflets and other materials to the stent. Examples will be shown and described later in this specification.

[0038] FIG. 6 shows yet another alternative

15 embodiment of stent frame 5010 (now numbered 5010c in FIG. 6). Once again, the same reference numbers used earlier are used again for generally similar elements in FIG. 6. Stent 5010c is basically the same as stent 5010, with the addition of a plurality of anchor

20 members 5201 that are resiliently biased to incline outwardly from annulus inflow portion 5200. During delivery of the valve into a patient in an annularly compressed or collapsed condition, anchor members 5201 can be deflected substantially parallel to the

25 longitudinal axis of the valve. When the valve is released from such annular compression for deployment in the patient (e.g., by pushing the valve out of the distal end of a delivery tube that keeps the valve annularly compressed), anchor members 5201 spring out

30 as shown in FIG. 6. In this condition anchor members 5201 engage (e.g., penetrate) the adjacent native tissue of the patient and thereby help to hold the valve in place in the patient. (FIG. 3 again

applies to the deployed condition of the FIG. 6 embodiment.)

[0039] It will be appreciated that anchors like 5201 can be used at any of many different locations on the stent frame 5010, etc., of any of the embodiments shown herein. As just one example of other possible locations for anchors like 5201, such anchors could be alternatively or additionally located on the upper (outflow) edge of any of the stent frame shown herein.

10 [0040] FIGS. 7a and 7b show illustrative embodiments in which an inflow-end cuff 5203 (e.g., of fabric) is included. Except for the addition of inflow cuff 5203, the embodiments shown in FIGS. 7a and 7b can be similar to any of the other embodiments shown herein. (FIGS.

15 7a and 7b include greatly simplified depictions of the leaflet structure 5500 in the open condition.) Inflow cuff 5203 preferably extends annularly all the way around the valve adjacent to its inflow edge. (As always throughout this specification, "inflow" refers

20 to the direction of blood flow through the valve after it has been implanted and is in use in a patient.) The cuff fabric material can be attached to the outside (FIG. 7a), the inside (e.g., between stent frame 5010d and leaflets 5500 as shown in FIG. 7b), or directly

25 below the stent frame in another embodiment. Inside and outside are preferred because this allows for better integration of the leaflet material 5500 onto the stent 5010d, because the leaflet materials utilize the presence of the cuff fabric material during

30 assembly and integration. This also provides a more durable design. When the valve is in the expanded state, the cuff fabric material should lie flat on the inside or outside of the stent frame 5010d. The



presence of the fabric 5203 helps promote tissue in-growth after the valve has been implanted. This helps to seal the valve against perivalvular leakage.

(FIG. 3 again applies to the deployed condition of the  
5 FIGS. 7a and 7b embodiments.)

[0041] FIGS. 8 and 9 show another illustrative embodiment in which stent frame 5010e includes commissure regions that are somewhat more post-like, as at reference number 5237. (FIG. 8 shows the apparatus  
10 in its annularly expanded, deployed condition. FIG. 9 shows part of the same apparatus in its annularly collapsed, delivery condition.) Making each prosthetic valve commissure region more like a single upstanding post 5237 may enhance each such commissure region's  
15 independent flexibility (i.e., its ability to flex independently of other parts of supporting structure 5010e). Amplifying the description of this aspect of FIGS. 8 and 9 somewhat, in embodiments of this type, each commissure tip 5236 of the valve is at  
20 the free end of a respective single structural member 5237 that is cantilevered from a respective single point on remaining structure of annulus inflow portion 5200.

[0042] FIGS. 8 and 9 also show examples of how stent  
25 frame 5010e may be provided with apertures 5239 for facilitating attachment of other components (e.g., leaflets 550) to the stent frame. Another possible use for apertures like 5239 is for helping to releasably secure a prosthetic valve in accordance with the  
30 invention to delivery system apparatus for the valve. For example, wires or suture material may pass through apertures like 5239 from and/or to delivery apparatus to help releasably hold the valve in the delivery

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apparatus until the valve is ready to be deployed into the patient. FIG. 3 again applies to deployment of the FIG. 8-9 embodiment.

[0043] FIG. 10 shows an example of a stent frame 5010f that (solely for purposes of illustration herein) has been cut along a longitudinal axis and then flattened. In the FIG. 10 embodiment the inflow edge of the stent frame (toward the bottom of FIG. 10) is scalloped or recessed so that it is relatively "high" in the vicinity of each commissure region 5236 and relatively "low" between each annularly adjacent pair of commissure regions. The high areas are pointed out by reference characters H, and the low areas are pointed out by reference characters L. Making the inflow edge of stent frame 5010f relatively high adjacent the aortic valve commissures helps the prosthetic aortic valve avoid possibly impinging on the patient's native mitral valve, and may also have other advantages.

[0044] FIG. 10 also illustrates some other possible variations. For example, FIG. 10 shows another possible arrangement of apertures 5239 like those mentioned above. FIG. 10 shows another arrangement of the circumferentially collapsible/expandable ring structures that can be used in areas 5100 and 5200. In this example these ring structures include four-sided, open-centered cells (e.g., 5105 and 5205) that can expand in the left-right direction as viewed in FIG. 10 to annularly expand the stent frame for deployment in the patient, or that can shrink in the left-right direction as viewed in FIG. 10 to annularly collapse the stent frame for delivery into the patient. FIG. 10 shows these cells 5105 and 5205 in their annularly

collapsed condition. A row of such cells can be thought of as two side-by-side serpentine or undulating rings that are 180° out of phase with one another and that have been joined together at adjacent peaks in their undulations. FIG. 10 also shows another example of use of barbs 5201 like those described earlier in this specification.

[0045] FIGS. 11 and 12 show a representative detail from FIG. 10. It will be understood that this type of feature can be used at any suitable location(s) in any of the embodiments shown herein. The feature detailed in FIGS. 11 and 12 is a rounded corner 5207 between otherwise relatively straight members of cells like 5205 or other similar serpentine or undulating ring structures. (Again, this feature can also be used elsewhere such as in region 5100.) FIG. 11 shows one representative rounded corner 5207 in an annularly collapsed structure. Note that in FIG. 11 rounded corner 5207 preferably has an overall C shape. FIG. 12 shows the same rounded corner after annular expansion of the structure. Now (i.e., in FIG. 12) corner 5207 has opened up somewhat to have a more nearly U shape. Use of these rounded corners helps to avoid stress concentration where the members of the cellular or serpentine structure change direction. This can improve the performance and extend the life of the structure. Also, upon expansion, these rounded corners tend to open up slightly (e.g., from a C shape to a U shape). This can facilitate leaflet attachment by providing locations through which suture material 5209 can be passed (e.g., as shown in FIG. 12).

[0046] FIG. 13 shows (using the same general type of depiction as in FIG. 10) yet another alternative

embodiment in which aortic outflow portion 5100 has more closed cells 5105 than annulus inflow portion 5200. This may facilitate annular expansion of aortic outflow portion 5100 to a larger diameter than annulus inflow portion 5200. FIG. 13 also shows another example of how and where aperture 5239 may be provided in stent frame 5010g to facilitate attachment of leaflets and other materials to the stent frame. (FIG. 3 again applies to deployment of embodiments like those shown in FIGS. 10 and 13.)

[0047] FIG. 14 shows that a valve in accordance with the invention may have fabric 5206 mounted internally of any portion of stent frame 5010 (the FIG. 14 example shows fabric 5206 between annulus inflow portion 5200 and leaflets 5500). FIG. 14 also shows that a valve in accordance with the invention may have fabric 5208 mounted externally of any portion of stent frame 5010 (again, the FIG. 14 example shows fabric 5208 around the outside of annulus inflow portion 5200). Although FIG. 14 shows fabric around both the inside and outside of a portion of stent frame 5010, it will be understood that fabric may be used in only one of these locations if desired. Some or all of the fabric like 5206 and/or 5208 may form the cuff 5203 shown in FIG. 7a or 7b.

[0048] FIG. 15 shows that a valve in accordance with the invention may have tissue material 5206a as a buffer between the stent frame 5010 and coapting leaflets 5500 to prevent abrasion of the leaflets by the stent frame and provide longer durability performance for the valve. In the example shown in FIG. 15, tissue material 5206a is between annulus inflow portion 5200 and leaflets 5500. Tissue

material 5206a is preferably thinner than the material used for leaflets 5500.

[0049] FIG. 16 shows (using the same general type of depiction as in FIG. 13) another illustrative embodiment of stent frame 5010h in which each commissure post region 5237 is bifurcated into two, substantially parallel, independently cantilevered post members 5237a and 5237b.

[0050] In general, it is preferred that the circumferential (annular, radial) collapse and re-expansion of prosthetic valves in accordance with this invention is elastic or at least mostly elastic. However, part or all of such collapse and/or re-expansion may alternatively or additionally result from use of shape-memory properties of the material of the stent frame (e.g., 5010) of the valve. As still another possibility, some or all of the collapse and/or re-expansion of the valve may be plastic. For example, such plastic re-expansion may be produced by inflation of a balloon (e.g., on a catheter) inside the valve.

[0051] It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, the number of undulations or cells used in aortic outflow portion 5100 and/or annulus inflow portion 5200 can be different (more or less) than the numbers shown in the FIGS. that form part of this disclosure.

What Is Claimed Is:

1. A prosthetic aortic valve comprising:  
an annular stent frame including (1) an  
annulus inflow portion configured for disposition, in  
use, adjacent a patient's native aortic valve annulus,  
5 (2) an aortic outflow portion configured for  
disposition, in use, in the patient's native aorta  
downstream from at least a portion of the patient's  
native valsalva sinus, and (3) a plurality of  
connecting struts that constitute substantially the  
10 sole connection between the annulus inflow portion and  
the aortic outflow portion, the annulus inflow portion  
defining a plurality of commissure tips that are spaced  
from one another in the annular direction around the  
annulus inflow portion, the commissure tips being the  
15 features of the annulus inflow portion that are closest  
to the aortic outflow portion, each of the connecting  
struts being connected to the annulus inflow portion  
only at points that are farther from the aortic outflow  
portion than the commissure tips, and each of the  
20 connecting struts being adjacent to an associated one  
of the commissure tips, at least one of the connecting  
struts being positioned for disposition, in use,  
adjacent each side of each of the patient's native  
aortic valve commissure tips, and each of the  
25 connecting struts, in use, bulging radially outwardly  
into the sinus of valsalva between the annulus inflow  
portion and the aortic outflow portion; and  
a plurality of valve leaflets supported  
by the annulus inflow portion.

2. The prosthetic aortic valve defined in claim 1 wherein the aortic outflow portion is integrally connected to the annulus inflow portion via the connecting struts.

3. The prosthetic aortic valve defined in claim 1 wherein the stent frame is elastically, annularly compressible to a first relatively small size.

4. The prosthetic aortic valve defined in claim 3 wherein the stent frame is elastically, annularly re-expandable from the first size to a second relatively large size.

5. The prosthetic aortic valve defined in claim 4 wherein the first size is suitable for delivery of the valve into the patient.

6. The prosthetic aortic valve defined in claim 5 wherein the second size is suitable for use of the valve in and by the patient.

7. The prosthetic aortic valve defined in claim 1 wherein the connecting struts that are adjacent each side of each of the patient's native aortic valve commissure tips are spaced apart from one another by a distance that is less than the distance between nearest connecting struts that are adjacent to two different ones of the commissure tips, all of said distances being measured at the level of the prosthetic valve commissure tips.

8. The prosthetic aortic valve defined in claim 1 wherein the annulus inflow portion is annularly continuous all the way around the valve.

9. The prosthetic aortic valve defined in claim 1 wherein the aortic outflow portion is annularly continuous all the way around the valve.

10. The prosthetic aortic valve defined in claim 1 wherein the annulus inflow portion has at least one interruption in the annular direction.

11. The prosthetic aortic valve defined in claim 1 wherein the aortic outflow portion has at least one interruption in the annular direction.

12. The prosthetic aortic valve defined in claim 1 further comprising a plurality of anchor members that are resiliently biased to incline outwardly from the stent frame.

13. The prosthetic aortic valve defined in claim 1 further comprising an annular cuff that is mounted on the annulus inflow portion.

14. The prosthetic aortic valve defined in claim 1 wherein each of the commissure tips is at a free end of a respective single structural member that is cantilevered from at least a respective single point  
5 on remaining structure of the annulus inflow portion.

15. The prosthetic aortic valve defined in claim 1 wherein each of the commissure tips is at a free apex of a V-shaped structure that is cantilevered



from at least a respective pair of points on remaining  
5 structure of the annulus inflow portion.

16. The prosthetic aortic valve defined in claim 1 wherein the stent frame defines a plurality of apertures for use in securing the leaflets to the stent frame.

17. The prosthetic aortic valve defined in claim 1 wherein the stent frame defines a plurality of apertures for use with a delivery system for the valve.

18. The prosthetic aortic valve defined in claim 1 wherein the annulus inflow portion includes a pair of structural members that are integral with one another at a curved corner that is initially C-shaped  
5 and that becomes more U-shaped when the structural members move away from one another in a direction that is annular of the valve.

19. The prosthetic aortic valve defined in claim 1 wherein both the aortic outflow portion and the annulus inflow portion include structure that undulates as one proceeds in an annular direction around the  
5 valve.

20. The prosthetic aortic valve defined in claim 19 wherein the structure of the aortic outflow portion that undulates has approximately a same number of undulations as the structure of the annulus inflow  
5 portion that undulates.

21. The prosthetic aortic valve defined in claim 19 wherein the structure of the aortic outflow

portion that undulates has more undulations than the structure of the annulus inflow portion that undulates.

22. The prosthetic aortic valve defined in claim 1 wherein an edge of the annulus inflow portion that is most remote from the aortic outflow portion includes a recessed edge portion aligned with at least  
5 one of the commissure tips, the recessed edge portion being closer to the aortic outflow portion than other portions of that edge of the annulus inflow portion.

23. The prosthetic aortic valve defined in claim 1 further comprising fabric inside at least a portion of the stent frame.

24. The prosthetic aortic valve defined in claim 1 further comprising fabric outside at least a portion of the stent frame.

25. The prosthetic aortic valve defined in claim 1 further comprising tissue material as a buffer between the stent frame and the leaflets to prevent abrasion and provide longer durability performance.

26. The prosthetic aortic valve defined in claim 25 wherein the tissue material is thinner than the leaflets.

27. The prosthetic aortic valve defined in claim 1 wherein the leaflets are made of a material selected from the group consisting of biological tissue, polymer, thin metal, and reinforced polymer.

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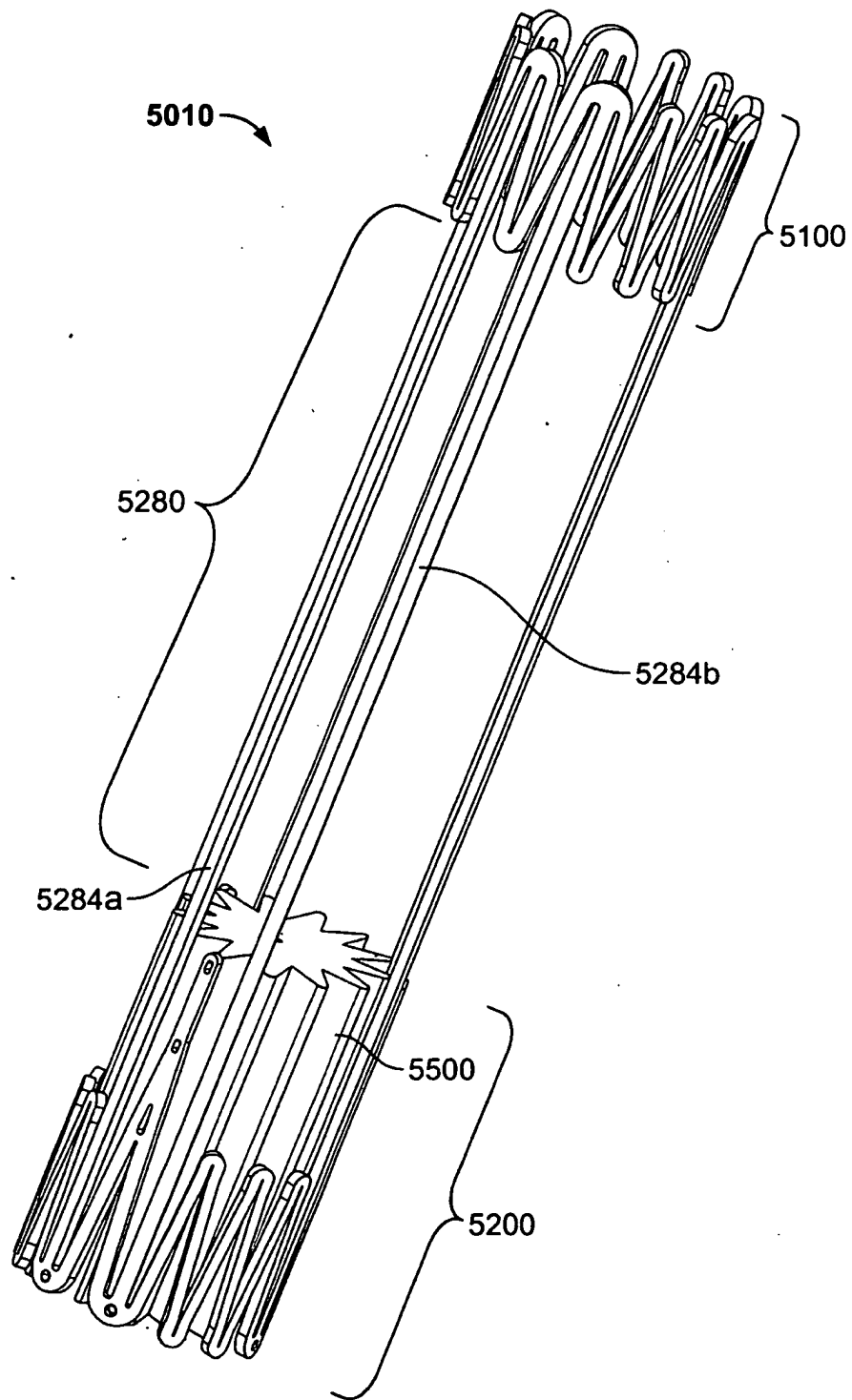


FIG. 1

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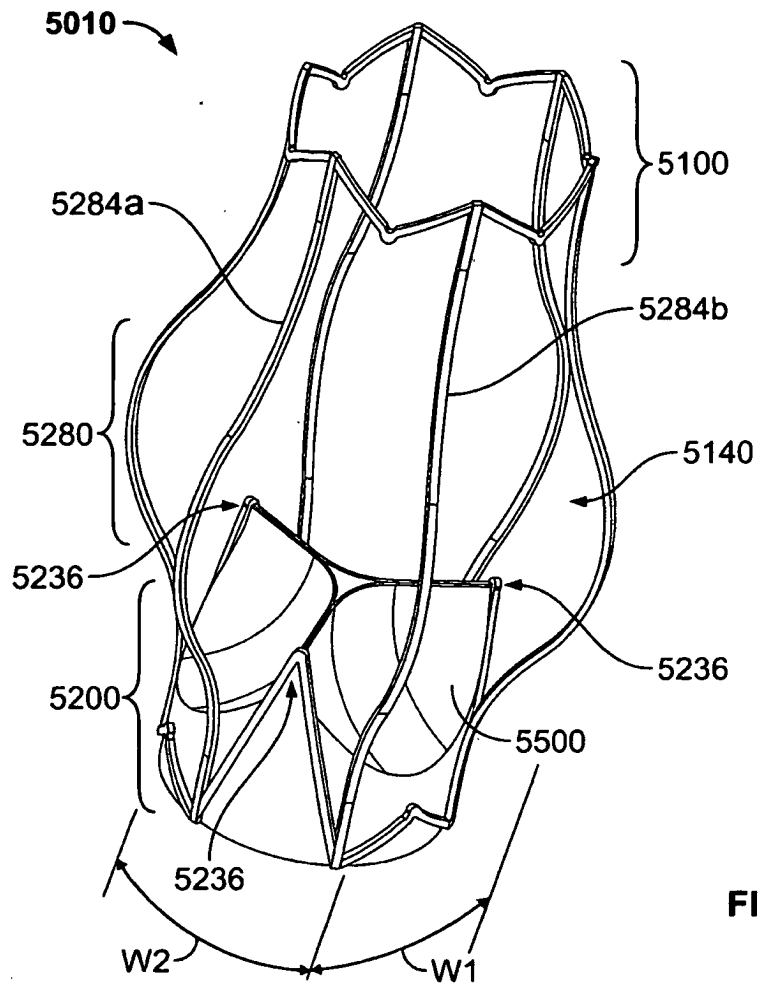


FIG. 2

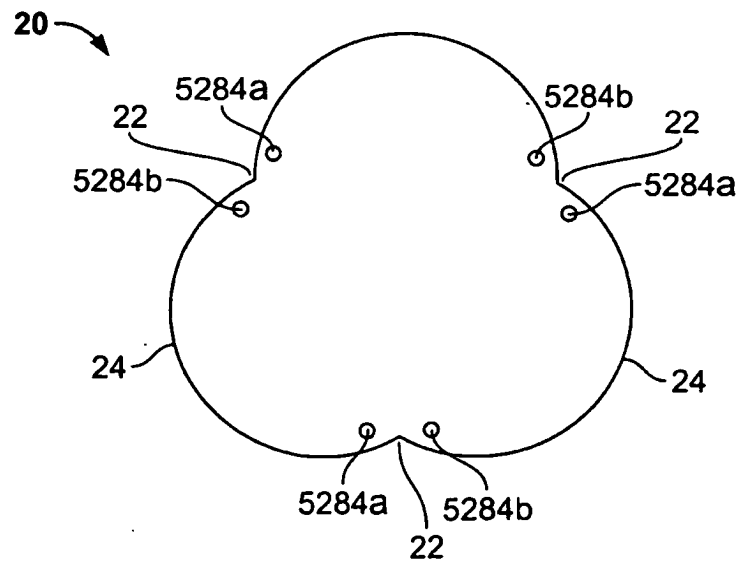


FIG. 3

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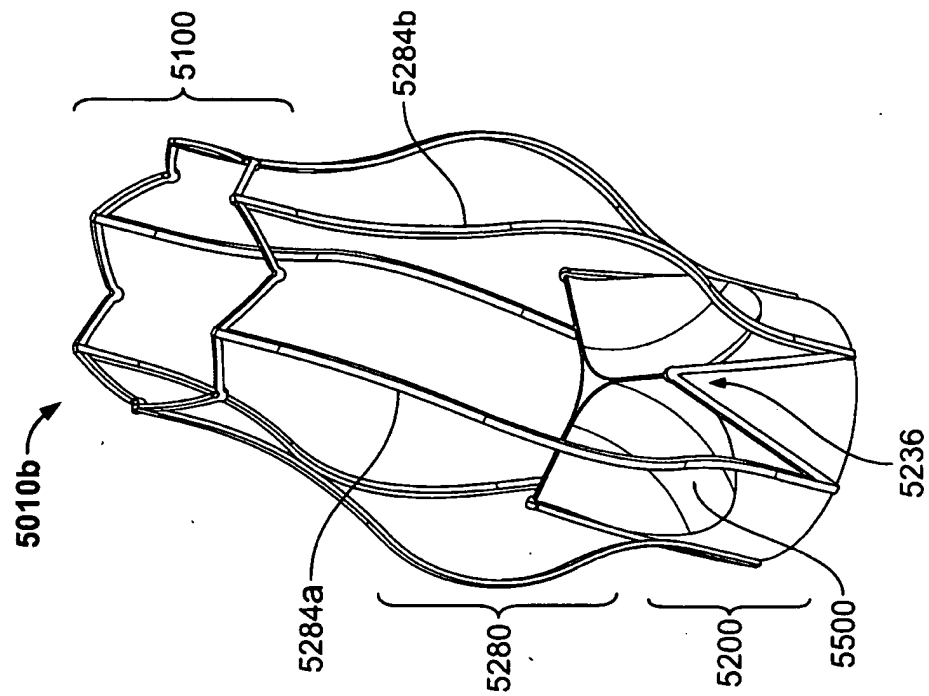


FIG. 5

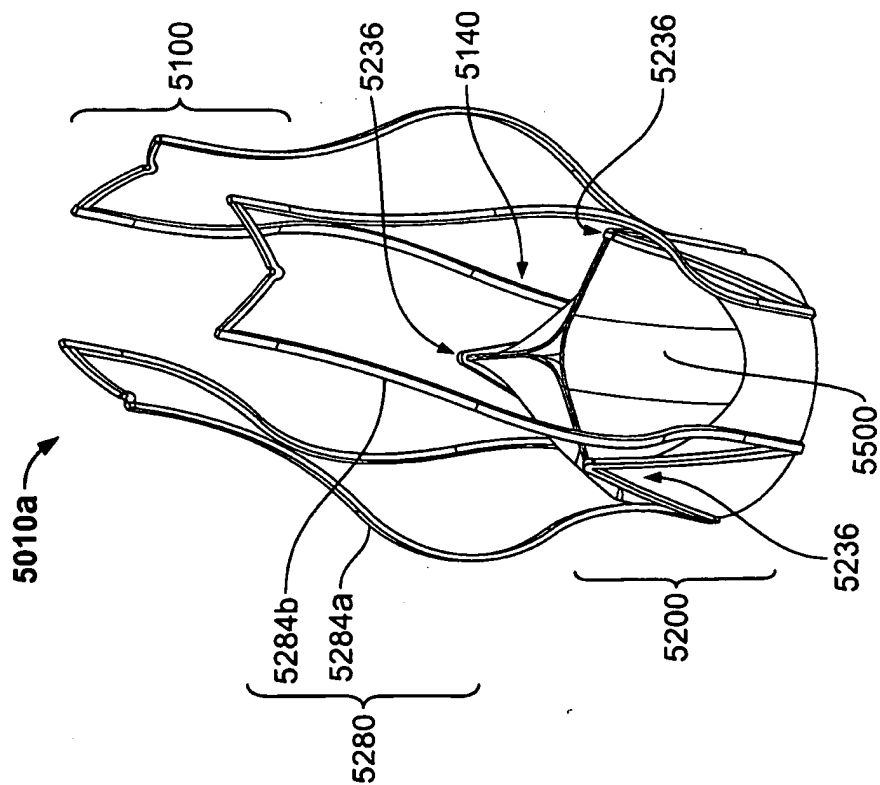


FIG. 4

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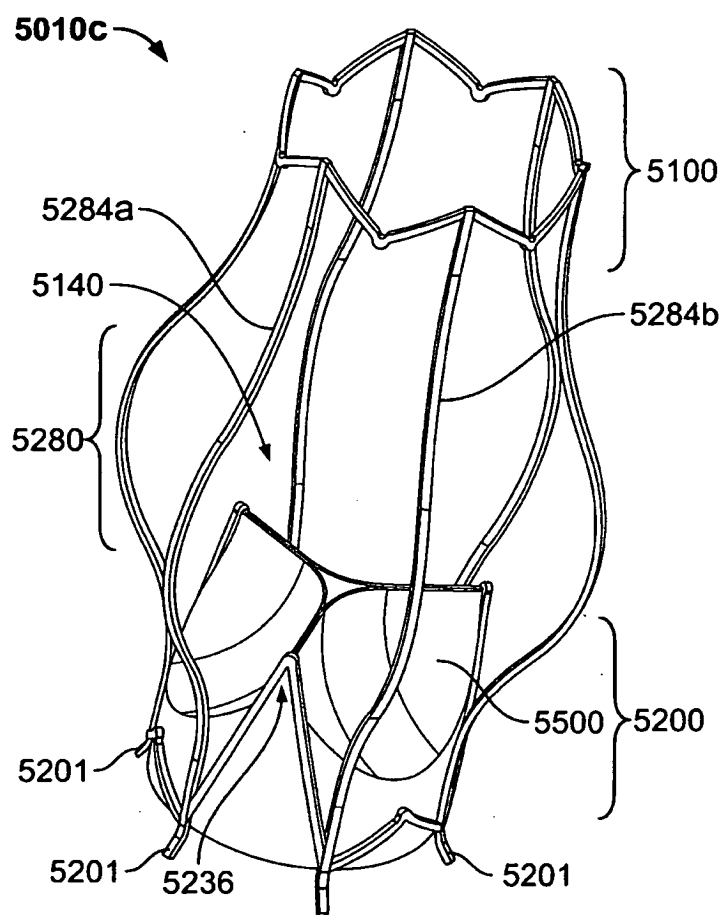
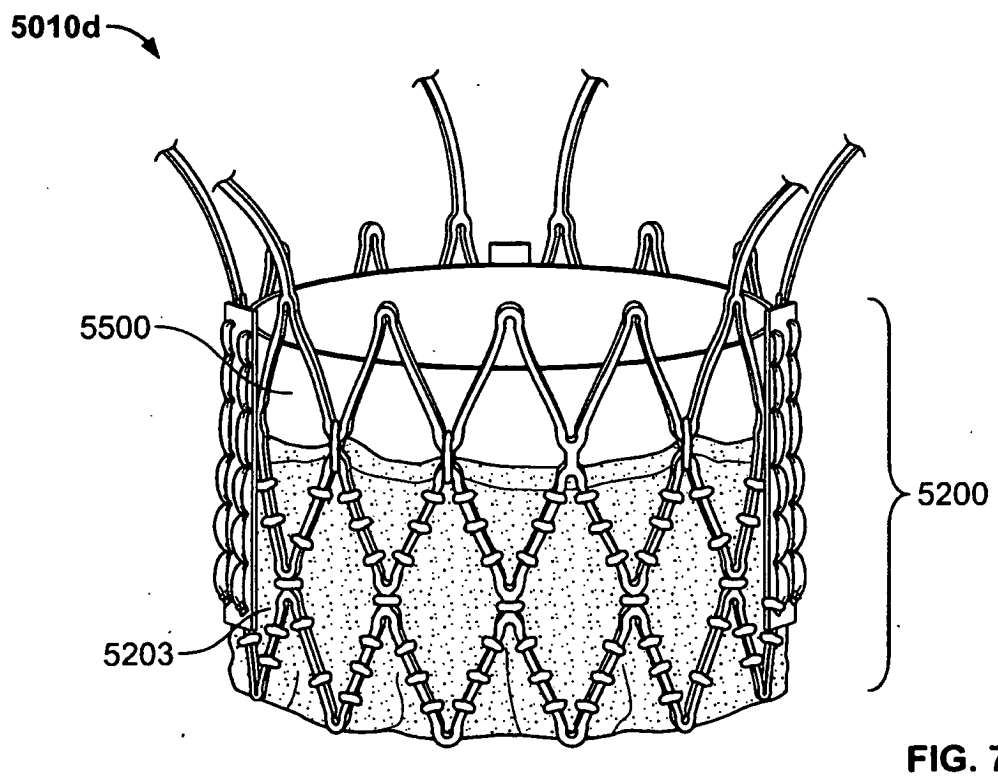
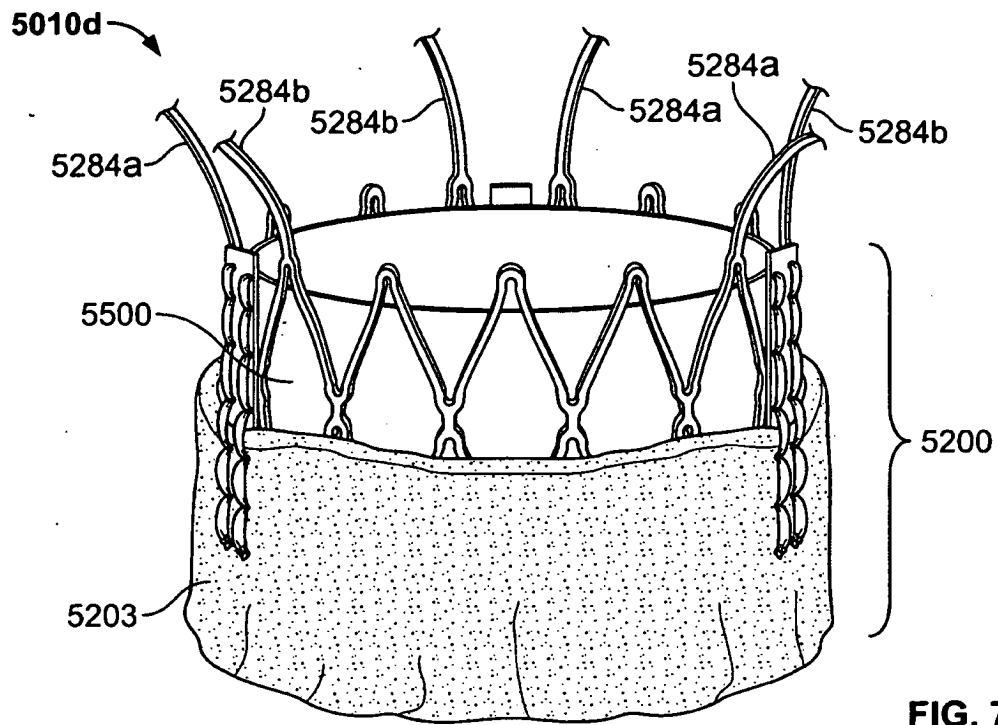


FIG. 6

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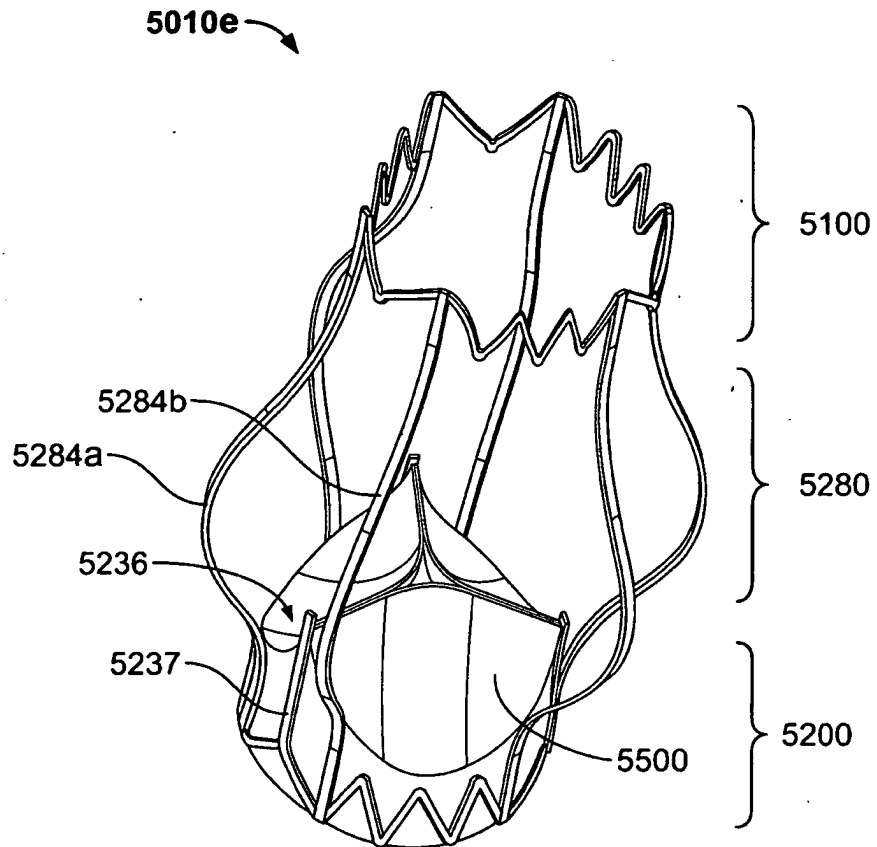


FIG. 8



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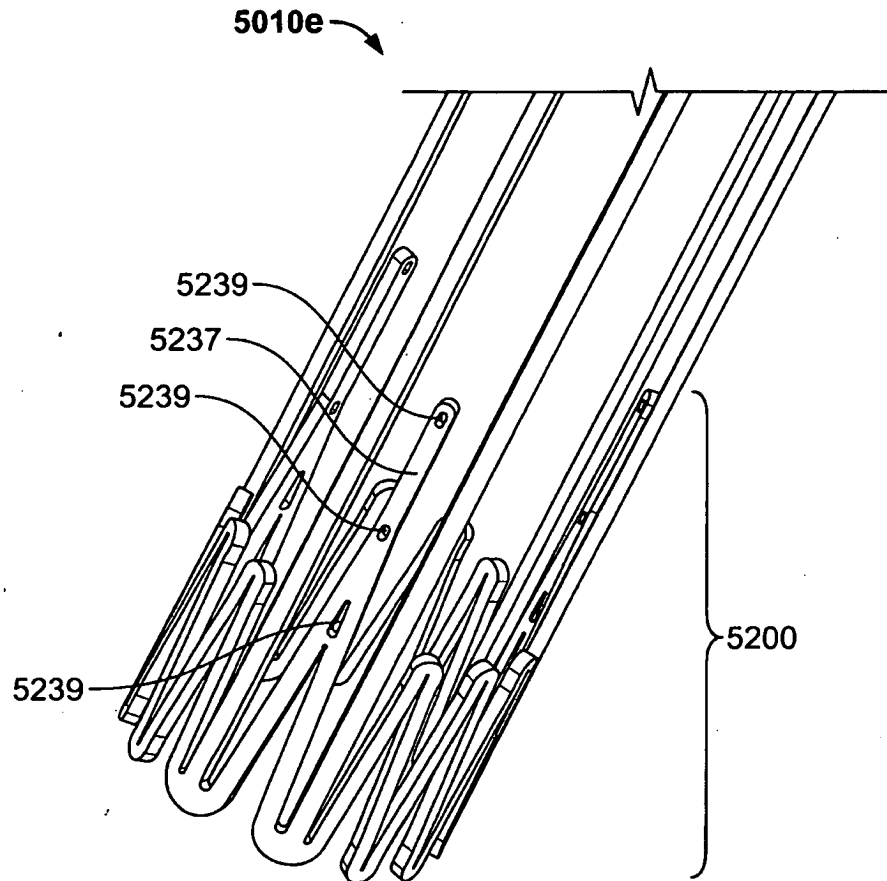


FIG. 9

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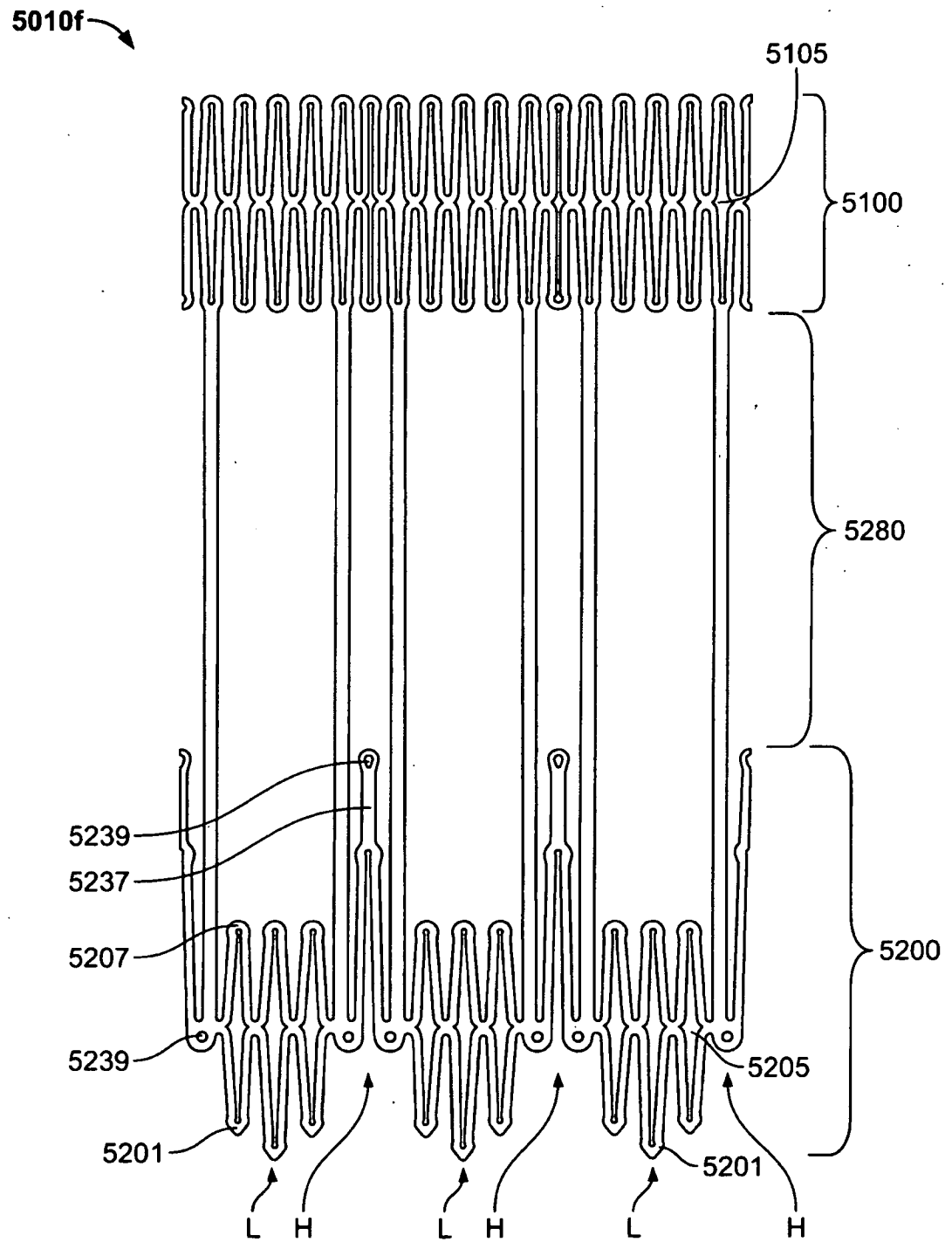


FIG. 10

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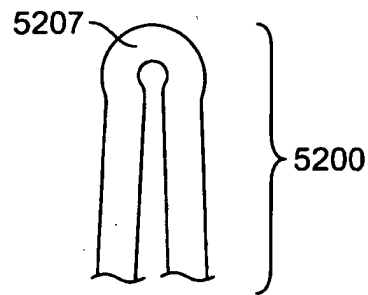


FIG. 11

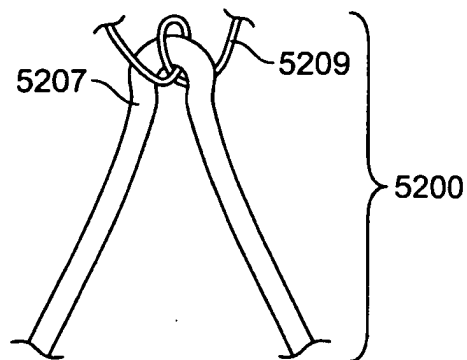


FIG. 12

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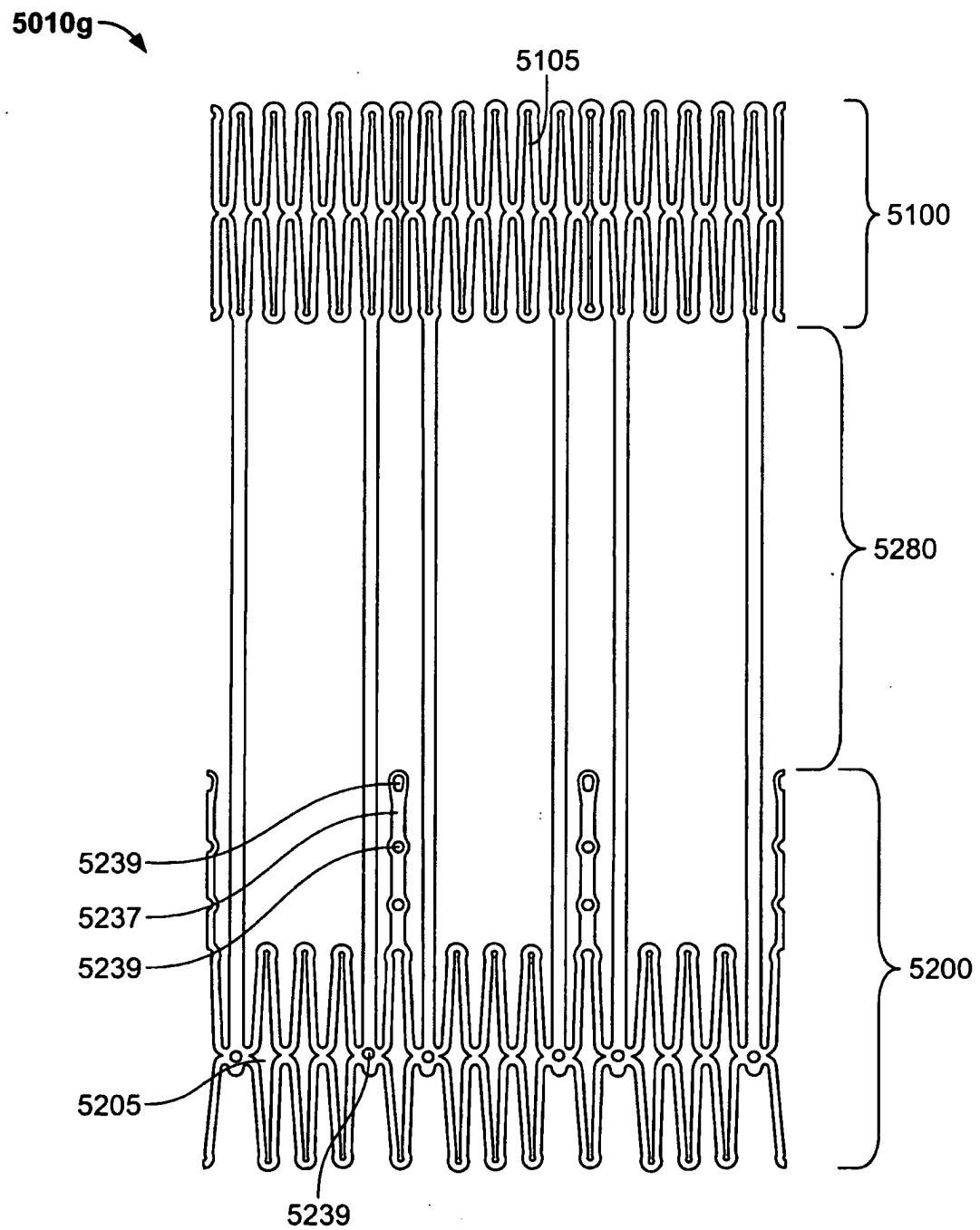


FIG. 13

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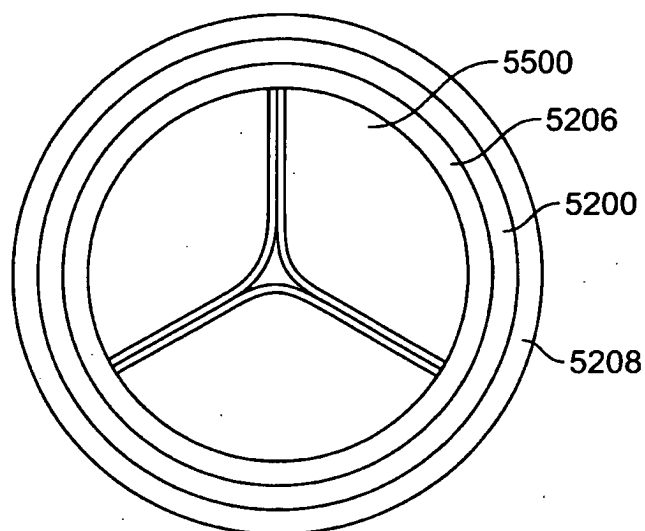


FIG. 14

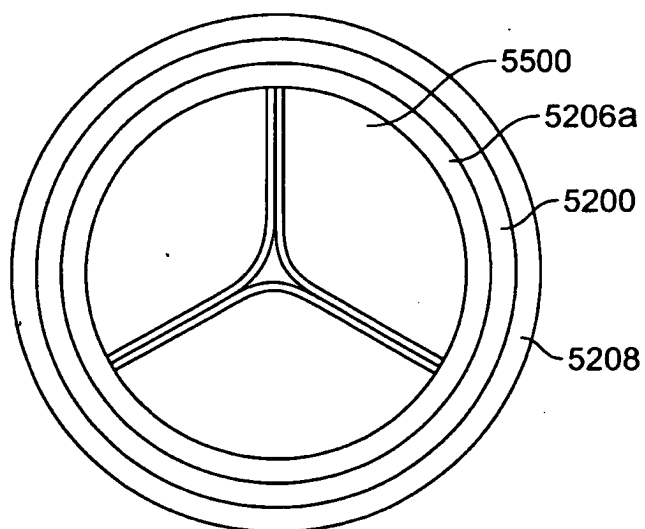


FIG. 15

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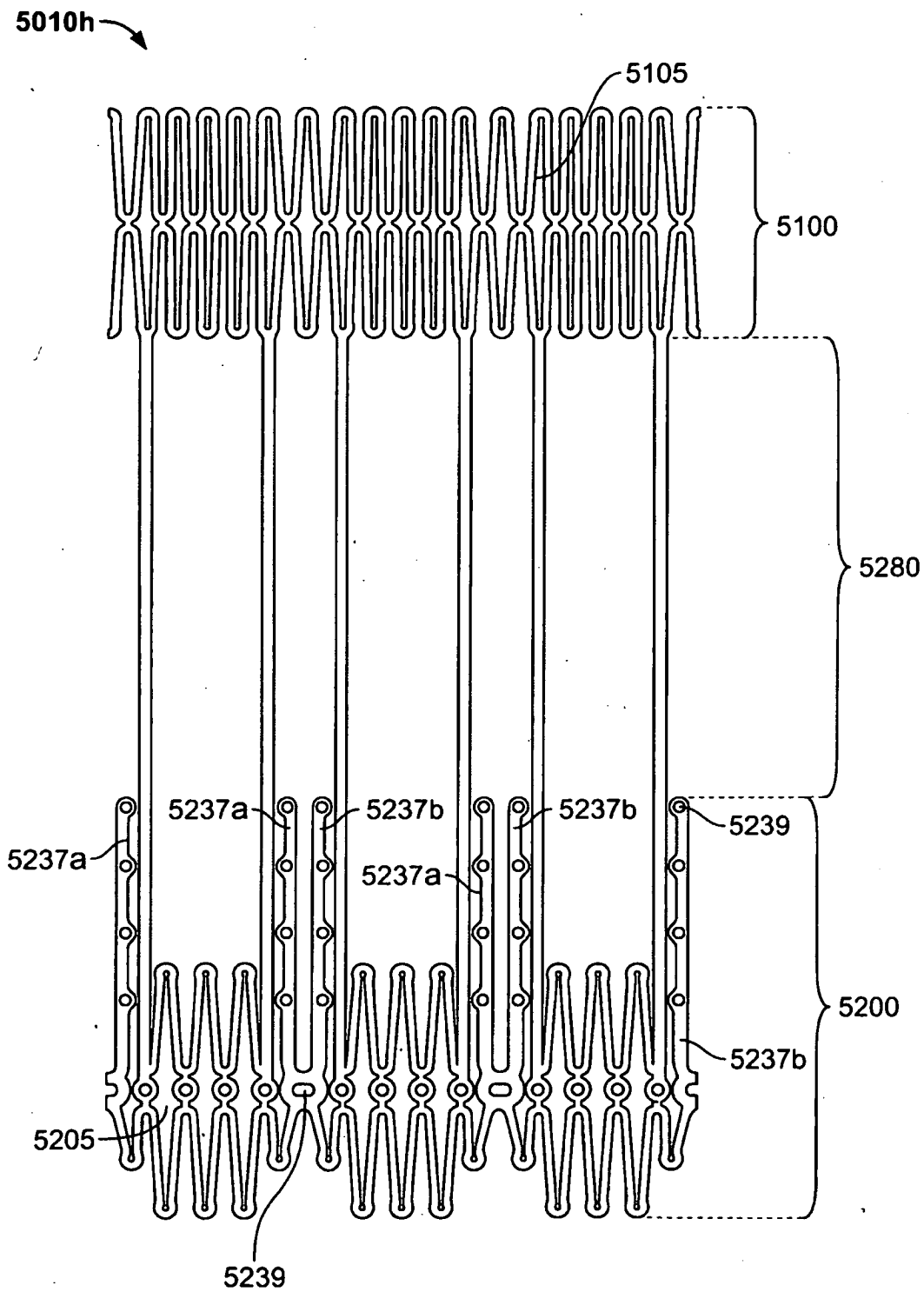


FIG. 16

# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2008/009950

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 690 515 A (SORIN BIOMEDICA CARDIO S R L [IT]) 16 August 2006 (2006-08-16)	1-6,8,9, 12-17, 19-21, 23-27
A	paragraphs [0037] - [0045], [0051] - [0060], [0064], [0080], [0088]; figures 3,4,8	7
A	US 2005/096734 A1 (MAJERCAK DAVID C [US] ET AL MAJERCAK DAVID CHRISTOPHER [US] ET AL) 5 May 2005 (2005-05-05)	1-9, 12-17, 19-21, 23-27
	paragraphs [0033], [0035] - [0040], [0046]; figures 1,2A,2F	
	-/--	

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

\* Special categories of cited documents:

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document but published on or after the international filing date

\*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*G\* document member of the same patent family

Date of the actual completion of the international search

7 November 2008

Date of mailing of the international search report

12/02/2009

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
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Fax: (+31-70) 340-3016

Authorized officer

Pantelidis, D

# INTERNATIONAL SEARCH REPORT

International application No

PCT/US2008/009950

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 2006/259137 A1 (ARTOF JASON [US] ET AL) 16 November 2006 (2006-11-16)</p> <p>paragraphs [0099] - [101104]; [0108], [0137], [0148], [0149]; figures 2,5,6A-6C,11,12,25A,25B</p>	<p>1-9, 12-17, 19-21, 23-27</p>



# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2008/009950

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see annex

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-9,12-17,19-21,23-27

A prosthetic aortic valve as defined by the combined subject-matter of claims 1 and 7.  
---

2. claims: 10,11

A prosthetic aortic valve as defined by the combined subject-matter of claims 1 and 10.  
---

3. claim: 18

A prosthetic aortic valve as defined by the combined subject-matter of claims 1 and 18.  
---

4. claim: 22

A prosthetic aortic valve as defined by the combined subject-matter of claims 1 and 22.  
---

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/009950

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 1690515	A	16-08-2006	AT 402672 T	15-08-2008
			WO 2006085225 A1	17-08-2006
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US. 2005096734	A1	05-05-2005	AU 2004289196 A1	26-05-2005
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			EP 1682048 A1	26-07-2006
			JP 2007509701 T	19-04-2007
			WO 2005046529 A1	26-05-2005
US 2006259137	A1	16-11-2006	WO 2008010817 A1	24-01-2008